Exhibit C

IN THE UNITED STATES DISTRICT COURT FOR THE

SOUTHERN DISTRICT OF WEST VIRGINIA, HUNTINGTON DIVISION

BEFORE THE HONORABLE ROBERT C. CHAMBERS, JUDGE

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CLAUDE R. KNIGHT and CLAUDIA STEVENS, individually and as personal representatives of the Estate of BETTY ERLENE KNIGHT, deceased,

Plaintiffs,

vs. No. 3:15-CV-06424

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., Volume 3
Pages 401 through 660

Defendant.
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REPORTER'S TRANSCRIPT OF PROCEEDINGS

JURY TRIAL

FRIDAY, OCTOBER 5, 2018, 9:00 A.M.

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(Appearances continued next page...)

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Proceedings reported by mechanical stenography, transcript produced by computer-aided transcription.

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Also Present:

CLAUDE R. KNIGHT, Plaintiff

what that information was, but certainly it's possible.
Q. Now, I think the jury has now seen various versions of the Pradaxa label at different points in time. But just to be clear, the FDA had to give approval on the label for Pradaxa during the entire time that the medicine has been on the market; correct?
A. Yes, even though there's at least one case where the approval came after. But, yes, that's true. That is required by the process.
Q. Okay. And it's not uncommon over time -- it's common practice that labels can evolve over the course of a medicine being on the market; correct?
A. Yes.
Q. All right. Do you know how many updates there have been to the Pradaxa label in the last eight years since the medicine's been on the market?
A. I would say more than a dozen, but I haven't counted them.
Q. Okay, fair enough. Each one of those labels had to be approved by the FDA; correct?
A. Yes.
Q. Now, you agree that the FDA has among the many professionals who work there medical doctors who are involved in evaluating the drug labeling that companies propose to the agency; correct?

paper about Pradaxa?

A. Yes. It's in --

Q. It starts on page 4.

A. Yes, dabigatran. I think we also, I think, looked at this.

Q. Yeah, this was right under the table I think that you talked about with Mr. Moskow.

A. Yes.

MS. JONES: And if we could just grab that section at the bottom. This is a little bit of a puzzle exercise piecing this together.

Q. But you see that's the section, the beginning of the section on Pradaxa, correct, that reference to dabigatran?

A. Yes.

Q. And then if you carry over to the next page, that discussion of dabigatran and possible interactions with P-gp inhibitors continues, correct?

A. Yes.

Q. There is no mention in that section, yes or no, to an interaction with Coreg, correct?

A. There is no -- specific in this section, you're correct, because that data has not been collected.

MS. JONES: Okay. We can take that down. Thank you, Mr. Reynolds.

Q. Okay. Dr. Plunkett, I want to turn now to talking a

relevant to what we've been talking about for the last day and a half or so.

You showed the jury the language from the CCDS and the SMPC that says Pradaxa is contraindicated in patients with severe renal impairment. Do you remember that?

A. Yes.

Q. And contraindicated means don't use it in these patients, right?

A. Yes. And I think I even described it as the risks would outweigh the benefits.

Q. Okay. Now do you know that Boehringer Ingelheim actually tried to get that language in the U.S. label for Pradaxa?

A. Yes, and I think we -- that was in another document earlier today.

MS. JONES: Your Honor, may I approach?

THE COURT: Yes.

MS. JONES: Dr. Plunkett, I've handed you what we've marked as Exhibits 5061 and 5062.

Q. Do you recognize those documents?

A. I'm not sure I've seen the e-mail, but I have seen, ah, the label.

Q. Okay.

MS. JONES: And so, Your Honor, we'd move for the admission of 5061 and 5062.

MR. MOSKOW: No objection.

Q. All right. And so this is the process that I think you described a little bit with the jury yesterday.

The company proposes a label. The FDA then has an opportunity to say here are some things we think should be different, correct?

A. Yeah. This is that negotiation I talked about.

Q. Okay. And then if you turn to Exhibit 5036, do you recognize that -- and this actually does have red lines -- the FDA's red line to the company's proposed labeling?

If you go to page 2 --

A. Yes.

Q. -- do you see that?

And if we go to the section we were just looking at entitled Contraindications, do you see that second bullet with that reference to severe renal impairment?

A. Yes.

Q. And what did the FDA do with that?

A. It has been struck.

Q. Okay. And then if we go to page 3 of that document in the core discussion section, there is the section entitled 2.5 Patients with Severe Renal Impairment.

Do you see that? It's about midway down the page.

A. Yes, I see that.

Q. And what the FDA did was they took out the contraindication, and they proposed instead that the

recommended dosage of Pradaxa in patients with severe renal impairment is 150 milligrams taken once every other day.

Do you see that?

A. Yes.

Q. And we now know that after some discussion and some analysis, they concluded that it would be the 75-milligram dose taken twice a day, correct?

A. Yes.

Q. So that language that you showed in the CCDS and the SMPC, that's language that the company proposed and the FDA literally struck from the label for Pradaxa, correct?

A. Yes. And they made a different proposal.

Q. Dr. Plunkett, we've talked a good bit about the FDA and its structure and the process for a medicine like Pradaxa, so I'm going to skip a lot of that discussion, but I did want to just ask you one question.

The company, as part of its development of Pradaxa, did both preclinical and clinical studies, correct?

A. Yes.

Q. And that means studies that involved humans and some that involved animals, correct?

A. Yes.

Q. All right. And Boehringer shared every one of those studies with the FDA, both the preclinical and the clinical studies, correct?

A. That's my understanding, yes.
Q. And when BI submitted Pradaxa for approval by the FDA, the FDA got all of the raw data from the RE-LY trial, correct?
A. Yes, they were given the raw data.
Q. Okay. And BI also submitted all of the PK data for Pradaxa that served as the basis for the RE-LY -- excuse me -- the Reilly exposure paper that you talked about yesterday, correct?
A. The raw data went in, yes, that is true.
Q. And also as part of that process, do you know that the company submitted analyses of its data from RE-LY to the FDA in something called a clinical overview document?
A. Yes, I'm aware of that document.
Q. And is that a document that you reviewed as part of your work in this case?
A. Yes, I have seen that document.
MS. JONES: May I approach, Your Honor?
THE COURT: Yes.
BY MS. JONES:
Q. Dr. Plunkett, do you recognize Exhibit 5084?
A. Yes, I do.
Q. Do you recognize that as the clinical overview document that we were just discussing a minute ago?
A. Yes. I think -- I assume this is what you were referring to, yes.

of who it has to go to.

THE COURT: Well, I think if you rephrase it, you can ask it.

MR. MOSKOW: Okay. I'll rephrase it.

THE COURT: Okay. How do you intend to rephrase it?

MS. JONES: No, Neal, he wants to know how you are going to rephrase it.

MR. MOSKOW: I will rephrase the question, and it will be something to effect of, now, Doctor, in reaching your opinions in this case, did you have an understanding as to who the warning should go to?

THE COURT: I think that's fair enough.

MS. JONES: I still think that speaks to a legal issue. I mean --

THE COURT: It has an implication for the legal issue, but it's -- I will permit that.

MS. JONES: Okay. Thank you, Judge.

(Bench conference, concluded.)

THE COURT: All right. Rephrase your question.

MR. MOSKOW: Yes, Your Honor. Thank you.

Q. Dr. Plunkett, in reaching your opinions in this case, did you have an understanding as to who the warning should go to here in West Virginia?

A. Yes.

Q. And who is that?

A. To the patient. So the Medication Guide becomes the most important document.

Q. Even with that statement, I want to ask you a few questions about the doctor's label. All right?

A. Sure.

Q. And in particular, I want to ask you about this warning and precaution that says risk of bleeding -- and I'm looking at Exhibit 5884 right now.

A. Uh-huh.

Q. Risk of bleeding. Pradaxa can cause serious and sometimes fatal bleeding. Promptly evaluate signs and symptoms of blood loss.

Do you recall that?

A. Yes.

Q. And you were asked whether it was a strong warning.

Do you recall your answer to that?

A. Yes. I said it was.

Q. Okay. And you were asked whether it was a serious warning.

Do you recall your answer to that?

A. Yes, I do. I said it was.

Q. I have a question for you. Is it a complete warning?

A. No, and that's my issue.

Q. Explain that to the jury.

A. So it is well known by scientists and physicians, based on

Q. And do you see that that is the Medication Guide?
A. Yes.
Q. Can you tell the jury whether there were any changes that the FDA recommended to the Medication Guide?
A. There is none.
Q. Well, I mean, they did some indenting of bullet points.
A. Well, I meant substantive changes.
Q. Okay. All right. Let's look at Exhibit 5036. Can you look at pages 22, 23, 24.

Are there any changes that the FDA recommended to that Medication Guide?
A. No.
Q. Have you seen any indication that BI proposed specific language regarding the drug never being tested in people with severe kidney problems, that the 75-milligram dose had never been tested, that people should not take Pradaxa and Coreg, that there was no reversal agent, and that you are more likely to have a GI bleed with Pradaxa than with warfarin?

Have you seen any evidence that any of those statements were proposed to be put in the Medication Guide?
A. No, I've not seen any indication that that was ever proposed.
Q. Doctor, you were shown many, many documents today including -- and yesterday including one of them Exhibit 5827, which was the summary review document.

summarizes the most important information about Pradaxa.

Do you believe that the Medication Guide can summarize the most important information about Pradaxa if it doesn't include information on the important identified risk of increased gastrointestinal bleeding?

A. No, I do not. I think that's a very important -- was a major outcome from the trial.

Q. Doctor, I started my examination with you and I am going to end my examination today, to the extent that the Medication Guide does not include information about never having been tested in patients with severe kidney problems, that the 75-milligram dose was never tested, that people shouldn't take Pradaxa and Coreg, that there is no reversal agent, and that there is no information about the -- or I'm sorry -- and the issue of GI bleeding, have you formed an opinion as to whether the Medication Guide fairly, accurately and completely describes the most important information about Pradaxa to patients here in West Virginia?

A. I have.

Q. And what is that opinion?

A. That it does not. And these are the areas that I believe are missing, although I would make one small change, never tested in AFib patients with severe renal impairment.

Q. Fair enough.

And, Doctor, are all of the opinions that you've given

CERTIFICATION:

We, Kathy L. Swinhart, CSR, and Lisa A. Cook, RPR-RMR-CRR-FCRR, certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter as reported on October 5, 2018.

October 6, 2018
DATE

/s/ Kathy L. Swinhart
KATHY L. SWINHART, CSR

/s/ Lisa A. Cook
LISA A. COOK, RPR-RMR-CRR-FCRR